DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0019]

Draft Guidance for Industry and Food and Drug Administration Staff on Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle'' dated January 2005. The draft guidance document serves as the special control to support the reclassification from class III to class II of the automated blood cell separator device operating on a centrifugal or filtration separation principle intended for the routine collection of blood and blood components. This draft guidance document describes a means by which the automated blood cell separator device operating by centrifugal or filtration separation principle may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to reclassify these device types into class II (special controls).

DATES: Submit written or electronic comments on the draft guidance by [*insert date 90 days after date of publication in the* **Federal Register**] to ensure their

adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time. Submit written comments on the information collection burden by [*insert date 60 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling the Center for Biologics Evaluation and Research Voice Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Kathleen E. Swisher, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, suite 200N, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle'' dated January 2005. This special control guidance identifies the relevant classification

regulation, which provides a description of the applicable automated blood cell separator. In addition, other sections of this special control guidance list the risks to health identified by FDA and describe measures that, if followed by manufacturers and combined with general controls, will ordinarily address the risks associated with these automated blood cell separators.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Comments

The draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit written or electronic comments to ensure adequate consideration in preparation of the final guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. The Paperwork Reduction Act of 1995

The draft guidance document contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520).

Under the PRA, Federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on the following topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Draft Guidance for Industry—Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle

Under the Safe Medical Devices Act of 1990 (Public Law 101–629, 104 Stat. 4511), FDA may establish special controls, including performance standards, postmarket surveillance, patient registries, guidelines, and other appropriate actions it believes necessary to provide reasonable assurance of

the safety and effectiveness of the device. This draft guidance document serves as the special control to support the reclassification from class III to class II of the automated blood cell separator device operating on a centrifugal separation principle intended for the routine collection of blood and blood components; and, serves as the special control for the filtration-based device with the same intended use reclassified as class II in the **Federal Register** of February 28, 2003 (68 FR 9530).

For currently marketed products not approved under the premarket approval (PMA) process, the manufacturer should file with FDA for 3 consecutive years an annual report on the anniversary date of the device reclassification from Class III to Class II or, on the anniversary date of the 510(k) clearance. Any subsequent change to the device requiring the submission of a premarket notification in accordance with section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360) should be included in the annual report. Also, a manufacturer of a device determined to be substantially equivalent to the centrifugal or filtration-based automated blood cell separator device intended for the routine collection of blood and blood components, should comply with the same general and special controls.

The annual report should include, at a minimum, a summary of anticipated and unanticipated donor adverse device events that have occurred, such as those required under (§ 606.160(b)(1)(iii) 21 CFR 606.160(b)(1)(iii))[1] to be recorded and maintained by the facility using the device to collect blood and blood components, and that might not be reported by manufacturers under Medical Device Reporting (MDR). Also, equipment failures, including software, hardware, and disposable item failures' should be reported. The reporting of

[1] 21 CFR 606.160(b) ''Records shall be maintained that include, but are not limited to, the following when applicable: * * * (1)(iii) Donor adverse reaction complaints and reports, inlcuding results of all investigations and followup.''

adverse device events summarized in an annual report will alert FDA to trends or clusters of events that might be a safety issue otherwise unreported under the MDR regulation.

Reclassification of this device from class III to class II for the intended use of routine collection of blood and blood components will relieve manufacturers of the burden of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by reducing the burden. Although the special control guidance document recommends that manufacturers of these devices file with FDA an annual report for three consecutive years, this would be less burdensome than the current postapproval requirements under part 814, subpart E (21 CFR part 814, subpart E), including the submission of periodic reports under § 814.84.

Collecting or transfusing facilities, and manufacturers have certain responsibilities under the CFR. Among others, collecting or transfusing facilities are required to maintain records of any reports of complaints of adverse reactions (§ 606.170), while the manufacturer is responsible for conducting an investigation of each event that is reasonably known to the manufacturer and evaluating the cause of the event § 803.50(b)(2) (21 CFR 803.50(b)(2)). In the draft guidance document, we recommend that manufacturers include in their three annual reports a summary of adverse reactions maintained by the collecting or transfusing facility or similar reports of adverse events collected in addition to those required under the MDR regulation.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Annual Report	4	1	4	5	20

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on FDA records, there are approximately four manufacturers of automated blood cell separator devices. We estimate that the manufacturers will spend approximately 5 hours preparing and submitting the annual report. The total annual burden of this collection of information is estimated at approximately 20 hours.

Other burden hours required for proposed 21 CFR 864.9245 are already reported and approved under OMB control number 0910–0120 (premarket notification submission 510(k), 21 CFR part 807, subpart E), and OMB control number 0910–0437 (MDR). Currently, manufacturers of medical devices are required to submit to FDA individual adverse event reports of death, serious injury, and malfunctions (§§ 803.50 and 803.53). The manufacturer is responsible for conducting an investigation of each event and evaluating the cause of the event (§ 803.50(b)(2)).

The reporting recommended in the special control guidance document broadens the information to be reported by manufacturers to FDA. Although the manufacturer's reporting burden is increased, the collection burden remains unchanged. We are recommending that the manufacturer submit annually, for 3 consecutive years, a summary of all adverse events, including those reported under part 803. The Mandatory MedWatch Reporting Form 3500A: Codes Manual, contains a comprehensive list of adverse events associated with device use, including most of those events that we recommend summarizing in the annual report.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: March 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–????? Filed ??–??–05; 8:45 am]

BILLING CODE 4160–01–S